

**GYNÉTICS INC.**

**JACK STOVER**

**8:55 A.M. – THURSDAY, JUNE 29, 2000**

00N-1256

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Good morning, my name is Jack Stover and I am Chief Operating and Financial Officer of Gynétics Inc. headquartered in Belle Mead, NJ. I want to thank the FDA for allowing Gynétics to share our views on the questions and issues compiled in the Federal Register announcement of this meeting.

As you may know, Gynétics is a private company that was started in 1995. Our first pharmaceutical product, the PREVENT™ Emergency Contraceptive Kit, was the first FDA approved emergency contraceptive product. In early September 1998, we obtained approval and launched PREVENT™ shortly thereafter. In addition to PREVENT™, Gynétics also has a levonorgestrel-based emergency contraceptive and several new oral contraceptive regimens in development and distributes a disposable medical device. However, we would like to limit our remarks today to emergency contraceptives and the consideration of taking ECs over-the-counter.

"Experts estimate that as many as 1.7 million of the over 3 million unintended pregnancies occurring each year in the U.S. could potentially be prevented by use of emergency contraceptive pills", according to a study completed by Dr. Trussell published in Family Planning Perspectives in 1992. Additionally, research, studies and experience have shown that ECs are generally a safe and effective method of preventing pregnancy as a back-up method to regular contraception and can generally be used by women without the direct supervision of a health care provider.

The biggest challenges we face in expanding the use of emergency contraception are i) lack of awareness; ii) timing and accessibility; and iii) confusion around off-label usage. We at Gynétics feel that making ECs available, in a controlled manner over-the-counter, will help us effectively deal with these challenges.

After spending almost \$15.0 million in advertising and promotion since the launch of PREVENT™ in 1998, Gynétics has been able to only modestly increase the public

awareness of EC to less than 10% of our target market. Because of the sporadic use of ECs whereby many women may only use the product once in their lifetime, it creates many unique challenges to increasing awareness cost effectively. However, unless we are able to raise the broad based awareness of emergency contraception, it will never be as effective as it could be. The problems of awareness are only enhanced by:

- ◆ Private Practitioners who do not discuss ECs with patients on a routine basis and, as a matter of fact, generally don't even discuss contraception unless it is initiated by the patient.
- ◆ Oftentimes, women need ECs based on a contraceptive failure on a Friday or Saturday night. Availability of a medical practitioner and access to a pharmacy that has product on hand is very difficult, especially with a 72-hour window, even though PREVENT™ is available in 9 out of 10 of the largest drug store chains and most large distributors. And as we know, emergency contraceptives are more effective when taken as soon as possible after a contraceptive failure.
- ◆ Many pharmacies still operate under conscience clauses, and therefore, are but another obstacle for women obtaining EC.
- ◆ Surveys to The EC Hotline have confirmed that access is a problem – almost ¼ of the calls failed to obtain access to EC.
- ◆ Family Planning Clinics that are publicly funded generally do a very good job of communicating about EC to their patients but many close, move or are only open on a part-time basis, and therefore pose yet another barrier to women having access to EC.
- ◆ Confusion with "The Morning After Pill".

We at Gynetics believe that the availability of emergency contraception over-the-counter could certainly expand public awareness of ECs by way of the customary high levels and volumes of consumer advertising. Independent studies and evaluations we have participated in say ECs in the U.S. could be a \$100 million a year product with the proper level of support and advertising. Additionally, such advertising will of course emphasize that ECs are not as effective as regular birth control methods, nor will ECs protect against HIV and STDs, therefore, ECs should only be used as a back-up method. Going over-the-counter with ECs will cause a significant increase in awareness alone, improve availability and ease of access and further reduce unintended pregnancies as well as

abortions. With 24-hour pharmacies, grocery and convenience stores proliferating much of the country availability of ECs and awareness of ECs would simply be significantly expanded.

Emergency contraceptives are widely recognized as being "low risk" drugs. I have heard physicians say that cigarettes should require prescription, not ECs. ECs are also indicated through self-diagnosis, like headaches. A woman knows if she has experienced unprotected sex within the last 72 hours. There are, as we know, significant risk factors such as smoking, obesity and a family history of blood clots however, these risks are now widely known since the same risk factors have existed with regular oral contraceptives since their introduction. However, the medical risks of a full-term pregnancy for a woman with these risk factors is probably greater than if she did take ECs.

As we all know, the off-label use of regular oral contraceptives being cut up with handwritten instructions and often no expiration dating and other procedures continues to a great extent today even with two FDA approved ECs available. This surely must confuse the consumer even more and certainly acts as a disincentive to legitimate pharmaceutical companies who must spend millions of dollars to obtain FDA approval of their products only to find other drugs being used off-label to disenfranchise their approved products.

In summary we at Gynetics believe that a well planned and controlled expansion of ECs as OTC products (initially with a good deal of control about them such as age restrictions, etc.) makes good sense. With OTC status ECs could be properly marketed and expand awareness and availability significantly from the low levels that we experience today. Additionally, the need for off-label use and all of the variations concocted to provide ECs should be significantly reduced with broad based but controlled availability over-the-counter.

Thank you for your time.